DEPARTMENT OF HEALTH AND HUMAN SERVICES

Extension of Designation of Scarce Materials or Threatened Materials Subject to COVID-19 Hoarding Prevention Measures; Extension of Effective Date with Modifications

AGENCY: Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) provides notice of the extension of the designation issued on July 30, 2020 designating health and medical resources necessary to respond to the spread of the virus associated with Coronavirus Disease 2019 (COVID-19) that are scarce or the supply of which would be threatened by excessive accumulation by people or entities not needing the excess supplies. This notice extends the designation and updates the list of scarce or threatened materials to include certain classes and sizes of hypodermic needles and syringes.

DATES: This action took effect [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and terminates on June 30, 2021.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: On March 23, 2020, and in response to the spread of the virus associated with COVID-19, President Trump signed Executive Order 13910 (Executive Order) to prevent hoarding of health and medical resources necessary to respond to the spread of COVID-19 within the United States. As provided in the Executive Order, it is the policy of the United States that health and medical resources needed to respond to the spread of COVID-19, such as personal protective equipment and sanitizing and disinfecting products, are appropriately distributed. This policy furthers the goal of protecting the Nation's healthcare systems from undue strain.

Through the Executive Order, the President delegated, to the Secretary of Health and Human Services (the Secretary), his authority under section 102 of the Defense Production Act of 1950, 50 U.S.C. 4512, as amended (the Act), to prevent hoarding of health and medical resources necessary to respond to the spread of COVID-19 within the United States, and his authority to implement the Act in subsection III of chapter 55 of title 50, United States Code (50 U.S.C. 4554, 4555, 4556, and 4560). Under this delegation and the Act, the Secretary may designate such resources as scarce materials or materials the supply of which would be threatened by such accumulation (threatened materials). The Secretary may also prescribe conditions with respect to accumulation of such materials in excess of the reasonable demands of business, personal, or home consumption. The Act prohibits any person or entity from accumulating designated materials (1) in excess of the reasonable demands of business, personal, or home consumption, or (2) for the purpose of resale at prices in excess of prevailing market prices.

The March 25 Designation Notice issued by HHS designates scarce materials or threatened materials that are subject to the hoarding prevention measures authorized under the Executive Order and the Act. *See* 85 FR 17592. (Mar. 30, 2020). Under 50 U.S.C. 4552(13), the term "materials" includes: "(A) any raw materials (including minerals, metals, and advanced processed materials), commodities, articles, components (including critical components), products, and items of supply; and (B) any technical information or services ancillary to the use of any such materials, commodities, articles, components, products, or items." For purposes of the March 25 Designation Notice, the term "scarce materials or threatened materials" means health or medical resources, or any of their essential components, determined by the Secretary to be needed to respond to the

spread of COVID-19 and which are, or are likely to be, in short supply or the supply of which would be threatened by hoarding. 85 FR at 17592. Designated scarce materials or threatened materials are subject to periodic review by the Secretary.

The designation is not a "regulation" under the Administrative Procedure Act (APA). See 50 U.S.C. 4559 (providing an exemption from the APA). To the extent that it is, the Secretary finds that, in light of the current pandemic, urgent and compelling circumstances make compliance with public comment requirements impracticable. See *Id*.

The March 25 Designation Notice was scheduled to terminate 120 days from the date of publication, unless superseded by a subsequent notice. Given the ongoing pandemic, the Secretary finds good cause to extend the March 25 Designation Notice, as modified by the June 30, 2020 and July 30, 2020 notices, through June 30, 2021. The Secretary also finds good cause to include the following modifications and additions to the list of scarce or threatened materials:

1. In FR Doc. 2020-06641 of March 30, 2020 (85 FR 17592), add the following text:
    (i) On page 17593, first column, (7) Sterilization services, add " or are authorized by FDA under section 564 of the FD&C Act for purposes of decontamination"
    (ii) On page 17593, first column, (11) Face masks, remove "PPE"
    (iii) On page 17593, first column, (12) Surgical masks, remove "PPE"

2. Add "Syringes and hypodermic needles (whether distributed separately or attached together) generally used in the United States for vaccinations that are

either:

(i) Piston syringes in 1 ml or 3 ml sizes that allow for the controlled and precise flow of liquid as described by 21 CFR 880.5860, that are compliant with ISO 7886-1:2017 and use only Current Good Manufacturing Practices (CGMP) processes; or

(ii) Hypodermic single lumen needles between 1" and 1.5" and 22 to 25 gauge between 1" and 1.5" and 22 to 25 gauge that have engineered sharps injury protections as described in the Needlestick Safety and Prevention Act, Pub. L. 106-430, 114 Stat. 1901 (Nov. 6, 2000) and Occupational Safety and Health Administration (OSHA) standard 29 CFR 1910.1030, Bloodborne Pathogens."

A copy of the Notice of the March 25 Designation, including the above modifications and those included in the June 30, 2020 and July 30, 2020 notices is provided below and also can be found on HHS's website.

Notice of Designation of Scarce Materials or Threatened Materials

Health or medical resources, or any of their essential components, determined by the Secretary of HHS to be needed to respond to the spread of COVID-19 and which are, or are likely to be, in short supply (scarce materials) or the supply of which would be threatened by hoarding (threatened materials). Designated scarce materials or threatened materials are subject to periodic review by the Secretary.

The following materials are designated pursuant to section 102 of the Defense Production Act (50 U.S.C. 4512) and Executive Order 13190 of March 23, 2020 (Preventing Hoarding of Health and Medical Resources to Respond to the Spread of COVID-19) as

scarce materials or threatened materials:

1. N-95 Filtering Facepiece Respirators, including devices that are disposable half-face-piece non-powered air-purifying particulate respirators intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates

2. Other Filtering Facepiece Respirators (e.g., those designated as N99, N100, R95, R99, R100, or P95, P99, P100), including single-use, disposable half-mask respiratory protective devices that cover the user's airway (nose and mouth) and offer protection from particulate materials at or greater than an N95 filtration efficiency level per 42 CFR 84.181.

3. Elastomeric, air-purifying respirators and appropriate particulate filters/cartridges

4. Powered Air Purifying Respirators (PAPR)

5. Portable Ventilators, including portable devices intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas

6. Sterilization services for any device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and sterilizers as defined in 21 CFR 880.6860, 880.6870, and 880.6880, including devices that already have FDA marketing authorization and those that do not have FDA marketing authorization but are intended for the same uses, or are authorized by FDA under section 564 of the FD&C Act for

purposes of decontamination

7. Disinfecting devices intended to kill pathogens and other kinds of microorganisms by chemical means or physical means, including those defined in 21 CFR 876.1500, 880.6992, and 892.1570 and other sanitizing and disinfecting products suitable for use in a clinical setting

8. Medical gowns or apparel, e.g., surgical gowns or isolation gowns

9. Personal protective equipment (PPE) coveralls, e.g., Tyvek Suits

10. Face masks, including any masks that cover the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels

11. Surgical masks, including masks that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials

12. PPE face shields, including those defined at 21 CFR 878.4040 and those intended for the same purpose

13. PPE gloves or surgical gloves, including those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and such gloves intended for the same purposes

14. Ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as “ventilators”), ventilator tubing connectors, and ventilator accessories as those terms are

described in FDA's March 2020 Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency located at https://www.fda.gov/media/136318/download

15. Laboratory reagents and materials used for isolation of viral genetic material and testing, such as transport media, collection swabs, test kits and reagents specific to those kits, and consumables such as plastic pipette tips and plastic tubes

16. Drug products currently recommended by the NIH COVID-19 Treatment Guidelines Panel, including (as of July 30, 2020) remdesivir and dexamethasone

17. Alcohol-based (over 60 percent) hand sanitizer and rubs.

18. Syringes and hypodermic needles (whether distributed separately or attached together) generally used in the United States for vaccinations that are either:

(i) Piston syringes in 1 ml or 3 ml sizes that allow for the controlled and precise flow of liquid as described by 21 CFR 880.5860, that are compliant with ISO 7886-1:2017 and use only Current Good Manufacturing Practices (CGMP) processes; or

(ii) Hypodermic single lumen needles between 1" and 1.5" and 22 to 25 gauge between 1" and 1.5" and 22 to 25 gauge that have engineered sharps injury protections as described in the Needlestick Safety and Prevention Act, Pub. L. 106-430, 114 Stat. 1901 (Nov. 6, 2000) and OSHA standard 29 CFR 1910.1030, Bloodborne Pathogens."

Authority: The authority for this Notice is Executive Order 13910 and section 102 of the

Defense Production Act of 1950, 50 U.S.C. 4512, as amended.

Norris Cochran,

Acting Secretary,

Department of Health and Human Services.

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